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EXAMINER	
FORD, JOHN K	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/056,237
Filing Date: January 25, 2002
Appellant(s): WISNIEWSKI et al.

Brett M. Hutton
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 30, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. This case is one of four related appeals that the Board is urged to take up simultaneously. The four applications are: SN 08/895,936, SN 10/057,610, SN 09/881,909 and SN 10/056237.

(3) Status of Claims

The statement of the status of the claims at the time of the final office action is correctly reproduced at the middle of page 4 of the Brief.

(4) Status of Amendments After Final

The statement of the status of the claims at the time of the final office action is correct.

(5) Summary of Invention

The summary of invention contained in the brief is deficient because it does not reference any portion of the specification nor make any reference to any drawing or reference numerals.

Figures 1 and 2 constitute the elected species and are described on page 15, paragraph 62 through page 19, paragraph 73 of the specification, incorporated here by reference.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Issue 3 is an issue that the Board of Appeals has no jurisdiction over. The P.T.O. does not decide such matters.

(7) Grouping of Claims

All of claims 1-8 and 27-42 (*sic* 27-34) stand or fall together as a group.

All of claims 35-42 stand or fall together as a separate group.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

"Large-Scale Freezing and Thawing of Biopharmaceutical Drug Product," Richard Wisniewski and Vincent Wu, (both employed at Genentech), Proceedings of the International Congress, Advanced Technologies for Manufacturing of Aseptic & Terminally Sterilized Pharmaceutical &Biopharmaceuticals, Basel, Switzerland, 17-19 February 1992 Convention Center Basel, pp. 133-139.

"Studies of Heat Transfer from a Vertical Cylinder, With or Without Fins, embedded in a Solid Phase Change Medium", B. Kalhori and S. Ramadhyani, Transactions of the ASME, Journal of Heat Transfer, Vol. 107, February 1985, pp. 44-51.

2,114,642	West	04/1938

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-8 and 27-42 rejected under 35 U.S.C. 112, second paragraph. This rejection is set forth in a prior Office Action, mailed on 06/02/2004, beginning on page 4 of the Appendix.

Claims 1-8 and 27-42 rejected under 35 U.S.C. 103(a). This rejection is set forth in a prior Office Action, mailed on 06/02/2004, beginning on page 8 of the Appendix.

(11) Response to Argument

Appellant's arguments begin on page 5 of the Brief and they are addressed here in the same order presented there:

1. "Biopharmaceutical Product"

In view of the explanation found in the first full paragraph of page 8 of the Brief, this rejection is withdrawn. Appellant has explained clearly, for the first time, what the Examiner perceived to be an inconsistency between the specification with regard to "buffers" and the definition offered by declarants Burman, Lawlis and Vetterlien.

2. Alleged improper combination of references.

Nothwithstanding that the term biopharmaceutical is definite, the Examiner is not persuaded by the argument that orange juice, milk, water and comestibles do not exhibit some of the same processing concerns as biopharmaceutical products. Other than opinion evidence, there doesn't appear to be any scientific evidence that this statement by Appellants is valid. In the course of prosecution, Appellants have submitted many prior art references for consideration, by the various examiners involved, related to freeze concentration of food products that are not biopharmaceuticals. It is inconsistent for Appellants to now argue this is irrelevant prior art when they themselves cited it to the office as relevant. As well, much of the prior art relied upon

in the rejections discusses the problem of attaining uniform freezing of liquid food products (such as West 2,114,642) not unlike those that Appellants have encountered in freezing biopharmaceuticals. Heat transfer scientists routinely make measurements of heat transfer for one material that can be extrapolated to other materials by known correlations such as Reynolds number, Nusselt number and Prandtl number.

Appellants want the Examiner and the Board to ignore the prior art related to freezing and thawing in general and to pretend as if the art of freezing biopharmaceuticals is so unrelated to freezing and thawing of other liquid solutions as to be uncombinable. No evidence is offered to support this proposition, which is self-serving at its core. Appellants here did not invent the freeze tank for biopharmaceuticals. It was invented long before (in 1992) and is now in the public domain and also apparently the intellectual property of Genentech. All appellants have done is to make an obvious modification for the prior art by substituting a centrally mounted cooling structure shown by Kaldori and Ramadhyani for that disclosed in the 1992 Wisniewski and Wu prior art.

i. 1992 Wisniewski and Wu publication

Appellant's make a whole service of self-serving statements about this prior art (including that the fins were small and thin and were designed only to ... etc.) All of this is not found in the reference itself, but instead comes from Mr. Wisniewski's extremely spotty memory of this device. First of all, the fins are sizeable both as shown in the reference itself and in Mr. Wisniewski's first declaration Exhibits B-D. This was contradicted, as have a number of Mr. Wisniewski's assertions, by the second Wisniewski declaration. Mr. Wisniewski has remembered and then apparently forgotten

so many important facts about the prior art that the Examiner is unsure, beyond the reference itself what constitutes reliable information. Moreover, Mr. Wisniewski refuses to contact Genentech or Mr. Wu (the co-author of the 1992 article) to see if the relevant dimensions of the device can be ascertained.

ii. The 1986 Kalhori Ramadhyani Article

While counsel doesn't want to admit it, this 1986 article clearly discloses a centrally mounted structure with fins that is extremely efficient at both freezing and thawing the contents of the tank. Dovetailing with his first argument, the fact that paraffin, a phase change material with precise characteristics that make it ideal for heat transfer research, is used in the 1986 article is argued to somehow make it completely irrelevant to processing biopharmaceuticals. On top of that counsel argues, without a single supporting bit of supporting evidence, that the 1986 and 1992 prior art "involve different principles of freezing." This is nonsense. Liquid-to-solid phase change (freezing) is the same phenomena regardless of the composition of the liquid to be frozen. The fact that the 1992 prior art uses finned tubes in the central structure teaches toward the 1986 prior art not away from it. Furthermore the 1986 prior art is listed in the appendix (list of references) of the 1996 re-print of the 1992 article, making the argument that it is somehow irrelevant completely hypocritical. One of ordinary skill in the art would have certainly been motivated to look for devices that produce "superior heat transfer characteristics." The Examiner concludes in the final rejection:

"To have replaced the centrally mounted heat exchanger and fins of the 1992 article by Wisniewski and Wu disclosed in Figure 1 with the heat exchanger and fins shown by Kalhori and Ramadhyani in Figure 3 [to] improve heat transfer and to facilitate ease of construction as

well as to facilitate easy removal of the frozen mass would have been obvious to one of ordinary skill in the art."

Counsel does not present even a single argument against the three motivational reasons given by the Examiner.

The only argument counsel can muster is the fact that no human being [including Mr. Wisniewski] can accurately predict such results [meaning the actual temperatures within a partially frozen mass undergoing freezing, if the quote was taken in context] Purporting to have such ability only diminishes one [meaning Mr. Wisniewski's, if the quote was taken in context] credibility.

This quote does not mean that those of ordinary skill in the art cannot make obvious improvements to known devices using well known, and in this case tested, alternative devices (namely the finned centrally mounted, heat exchanger of the 1986 article).

The 1986 article states that as well when discussing the finned heat exchanger in the penultimate and last paragraph on page 50, to wit:

"However there is a significant enhancement in the total heat transfer due to the addition of fins. The augmentation of the rate of heat transfer is in accordance with expectations."

Thus, as the Board can now appreciate, the prediction of the temperature distribution around the finned cylinder is a moving boundary problem in a complex geometry that is amendable only to numerical solution or experimental measurement (not to the type of mental experiment done by Mr. Wisniewski in the preparation of Exhibits B-D of his first declaration), however, the augmentation of the rate of heat transfer by adding bigger fins is an entirely expected results (as evidenced by the aforementioned quote from the 1986 article) that counsel

does not want to acknowledge. Counsel's clumsy attempt to equate the impossibility of predicting actual temperatures in a partially frozen mass by mental experiments (as Mr. Wisniewski engaged in during the preparation of Exhibits B-D of his first declaration) with the obviousness of substituting one known finned heat exchanger for another simply doesn't make his case. It confuses two different things and indirectly undermines the credibility of Exhibits B-D of Mr. Wisniewski.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

John K. Ford
Primary Examiner

jkf
December 29, 2004

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